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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/816,636	04/01/2004	Patrick T. Petruno	10040213-1	1047

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EXAMINER
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YU, MELANIE J

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 05/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/816,636	<b>Applicant(s)</b> PETRUNO ET AL.	
	<b>Examiner</b> Melanie Yu	<b>Art Unit</b> 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 24 March 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 11, 12, 21-26 and 30-36 is/are pending in the application.
- 4a) Of the above claim(s) 32-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11-12, 21-26, 30 and 31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                                    | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 24 March 2006 has been entered.

### ***Status of the Claims***

2. Claims 1-10, 13-20 and 27-29 have been canceled. Claims 11, 12, 21-26 and 30-36 are currently pending in this application.

### ***Election/Restrictions***

3. Newly submitted claims 32-36 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Inventions of group I, claims 11, 12, 21-26 and 30-31 and group II, claims 32-36, are directed to related products. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the products of group I and group II are mutually exclusive, are not obvious variants and have a materially different design because the products of group I and group II have different features which are not required of the product of the other group. The product of group I requires a light source positioned to illuminate a target area on a medium, which is not required of the product of group II. The product of group II requires a user interface that provides test results, which is not required of the product of group I.

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Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 32-36 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 11, 12 and 21-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crosby (US 6,217,744) in view of Straus (US 2003/0082516).

Regarding claims 11 and 23, Crosby teaches a test system comprising: a medium (porous membrane with chemical reagents, col. 6, lines 6-11; chemistry analysis strip, col. 6, lines 35-39) comprising a labeling substance that comprises a fluorescent structure (porous membrane comprises reagents for chemical analysis, in optical measurements fluorescent markers are reagents for analysis, col. 3, lines 28-37; col. 5, lines 35-47; col. 6, lines 46-50) a light source positioned to illuminate a target area on the medium (diode laser must be illuminating a target area on the medium comprising the chemical reagents in order to detect fluorescence, col. 5, lines 39-47); a photodetector positioned to measure light from the target area of the medium (chemical reagents are the fluorescent structure and are in the porous membrane, the photodetector must be positioned to measure light to provide detection of light from a diode laser, col. 5, lines 35-47); wherein the photodetector and the medium are contained in a single-use module (optical components and porous membrane are part of the disposable device, optical components comprise the photodetector, col. 5, line 64-col. 6, line 13); and a reusable module having a receptacle into which the single-use module can be inserted for communication of test signals between the single-use module and the reusable module (communication between disposable

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analysis device an information gathering and storage system, disposable device is single use and information gathering and storage system is reusable, col. 6, lines 57-67; col. 7, lines 37-45). Crosby fails to teach a specific target area on the medium at which the light source is positioned to illuminate and the fluorescent structure being a persistent fluorescent structure, ie. a quantum dot.

Straus teaches a medium (detection zone, par. 32) comprising a labeling substance that binds a quantum dot to a target analyte in a target area on the medium (quantum dot used as a fluorescent signal element for labeling a molecule, labeling molecules bound to cell, par. 69, 203-204), wherein the light source illuminates the target area of the medium (par. 128), in order to achieve high signal intensities.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the system of Crosby, a labeling substance that binds a quantum dot to a target analyte in a target area and a specific target area on the medium which the light source is positioned to illuminate as taught by Straus, in order to provide a label with a more stable and stronger signal.

With respect to claims 12 and 21, Crosby teaches the reusable module implementing a user interface capable of indicating a test result on a display (console is the information gathering and storage system and has a display screen to display results from the disposable device, col. 7, lines 37-50).

Regarding claim 22, Crosby teaches that the test signals are electrical signals (col. 7, lines 14-25).

Regarding claims 24 and 25, Straus teaches a photodetector positioned to measure light (photodetectors used to measure properties, par. 169, 222) that has a frequency characteristic of fluorescent light resulting from the light source illuminating the quantum dot (quantum dots generate strong fluorescent signal therefore the photodetector detects

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light that has a frequency characteristic of fluorescent light, par. 203), in order to detect fluorescence emitted by quantum dots.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the photodetector of Straus for the photodetector of Crosby when quantum dots are used as the indicator of Crosby.

5. Claims 11, 12, 21-23, 26 and 30-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crosby (US 6,217,744) in view of Daniels et al. (US 2002/0004246).

Regarding claims 11 and 23, Crosby teaches a test system comprising: a medium (porous membrane with chemical reagents, col. 6, lines 6-11; chemistry analysis strip, col. 6, lines 35-39) comprising a labeling substance that comprises a fluorescent structure (porous membrane comprises reagents for chemical analysis, in optical measurements fluorescent markers are reagents for analysis, col. 3, lines 28-37; col. 5, lines 35-47; col. 6, lines 46-50) a light source positioned to illuminate a target area on the medium (diode laser must be illuminating a target area on the medium comprising the chemical reagents in order to detect fluorescence, col. 5, lines 39-47); a photodetector positioned to measure light from the target area of the medium (chemical reagents are the fluorescent structure and are in the porous membrane, the photodetector must be positioned to measure light to provide detection of light from a diode laser, col. 5, lines 35-47); wherein the photodetector and the medium are contained in a single-use module (optical components and porous membrane are part of the disposable device, optical components comprise the photodetector, col. 5, line 64-col. 6, line 13); and a reusable module having a receptacle into which the single-use module can be inserted for communication of test signals between the single-use module and the reusable module (communication between disposable analysis device an information gathering and storage system, disposable device is single use and information gathering and storage system is reusable, col. 6, lines 57-67; col. 7, lines

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37-45). Crosby fails to teach a specific target area on the medium at which the light source is positioned to illuminate and the fluorescent structure being a persistent fluorescent structure, ie. a quantum dot.

Daniels et al. teach a labeling substance that comprises a quantum dot, which is a persistent fluorescent structure, the labeling structure being capable of binding the quantum dot to a target analyte (semiconductor nanocrystal is a quantum dot, par. 79; quantum dot is detection reagent, par. 111; quantum dot labels analyte, par. 137) in a target area on the medium (par. 25-27, Fig. 1) and wherein a light source illuminates the target area of the medium (test strip illuminated, par. 40), in order to provide a detection reagent that is capable of giving quantitative results for multiple analytes.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the labeling substance of the medium of Crosby, a labeling substance that binds a quantum dot to a target analyte in a target area that is illuminated by the light source as taught by Daniels et al., in order to provide indicator reagent unique tags for detection of biological molecules that further provide the ability to observe discrete optical transitions in a concentrated area which makes the detection more accurate. The tunable emission properties allow multiple analyte detection to be carried out in one test strip and greater sensitivity and dynamic range can be achieved relative to conventional detection reagents. Use of quantum dots in a test strip is also advantageous because a system can be designed to minimize substrate autofluorescence by selecting well-separated excitation and emission wavelengths.

With respect to claims 12 and 21, Crosby teaches the reusable module implementing a user interface capable of indicating a test result on a display (console is the information gathering and storage system and has a display screen to display results from the disposable device, col. 7, lines 37-50).

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Regarding claim 22, Crosby teaches that the test signals are electrical signals (col. 7, lines 14-25).

With respect to claim 26, Daniels et al. teach the medium comprising a later flow strip for performing a binding assay and the target area containing an immobilized substance that binds and holds a complex including the labeling substance and target analyte (par. 25-28).

With respect to claims 30 and 31, Crosby teaches a test system comprising a medium containing a labeling substance that comprises a fluorescent structure, but fails to teach a first and second type of quantum dot for binding to a target area and control area, respectively.

Daniels et al. teach a labeling substance comprising a first type of quantum dot that emits light having a first frequency; and a second type of quantum dot that emits light having the second frequency (par. 207 and 225), in order to provide a distinct emission characteristic for multiple analyte.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to use in the test system of Crosby, a first and second type of quantum dot that emit light at a first and second frequency, respectively, as taught by Daniels et al., in order to perform assays for multiple analyte in the same device, wherein the indicator has greater sensitivity and dynamic range for detecting multiple analyte in a sample on the same test strip and thus improves efficiency.

Daniels et al. teach the first type of quantum dot attached to a substance that binds to the target analyte and to the test area (detection complex comprising target analyte and quantum dot, a separate test region comprising a specific capture reagent exists to capture each detection complex therefore the first type of quantum dot is attached to a substance that binds the target analyte and the test region, par. 223); and the second type of



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quantum dot attached to a substance that binds to a control area of the medium (control region captures any excess detection complex, therefore, when multiple analyte are tested, a second quantum dot is used as indicated in par. 225, and a second quantum dot that is attached to a second target analyte would bind to the control area, par. 223-225 and par. 207).

### ***Response to Arguments***

6. Applicant's arguments with respect to claims 11, 12, 21-26 and 30-31 have been considered and have been withdrawn, but are moot in view of the new ground(s) of rejection. However, upon further consideration, a new ground(s) of rejection is made in view of applicant's amendment requiring the medium and photodetector positioned in a single use module which can be inserted into a reusable module.

### ***Conclusion***


No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Yu whose telephone number is (571) 272-2933. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
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